Class 1 Device Recall Puritan Bennett

Date Posted: October 28, 2014
Recall Status: Open
Recall Number: Z-0112-2015
Recall Event ID: 699320
Premarket Notification 510(K) Number: K13125

Product Classification: Ventilator, Continuous, Facility Use. Product Code CBK

Product: Covidien Puritan Bennett 880 Ventilator, Rx ONLY. Suitable for service in a hospital (institutions) and intra-hospital transport to provide continuous positive pressure ventilator for Neonatal (NICU) through Adult patient populations.


Recalling Firm: Nellcor Puritan Bennett Inc. (dba Covidien LP)

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=130226
11/10/2014
Manufacturer 6135 Gunbarrel Ave  
               Boulder, Colorado 80301-3214

Manufacturer Reason for Recall A software issue may lead to ventilator inoperative situations.

FDA Determined Cause DESIGN: Software Design

               The letter identified the affected product and the reason for the recall. Customers were
               provided actions to be taken, as well as, important safety reminders. The letter informed
               customers that they may continue to use their ventilators pending the software correction as
               long as two gas sources are connected to the ventilator at all times. Customers are to
               complete the attached acknowledgement and receipt form and fax it to Covidien at the
               number provided. For further assistance, customers are to contact the Technical Support
               Department at 1-800-255-6774.

Quantity in Commerce 324 units

Distribution Worldwide Distribution -- USA, including the states of CA, CO, FL, GA, KY, MA, MN, NC, NY,
                           OH, OK, PA, SC, TN, TX, UT, WI; and, the countries of Canada, Mexico, Saudi Arabia, South
                           Africa, and United Arab Emirates.

Total Product Life Cycle TPLC Device Report

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 § 5.52

2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database 510(K)s with Product Code = CBK and Original Applicant = COVIDIEN

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
14. /scripts/cdrh/cfdocs/cfStandards/search.cfm
15. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
16. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
17. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
18. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
19. /scripts/cdrh/cfdocs/cfCilia/Search.cfm
20. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm